



Fiscal Year 2018 Budget-in-Brief

Public Health and Social Services Emergency Fund

The Office of the Assistant Secretary for Preparedness and Response's (ASPR) budget request to Congress for fiscal year (FY) 2018 supports ASPR's mission of enhancing national health security; promoting community preparedness and resiliency; strengthening the nation's health and response systems; and building research and development partnerships with federal agencies, academic institutions, and private industry. ASPR serves as the principal advisor to the Secretary of the Department of Health and Human Services (HHS) on public health and medical emergency preparedness and response, including incidents covered by the National Response Framework. To support this mission, the FY 2018 budget request for ASPR is \$1.5 billion, an increase of \$107 million above the FY 2017 level. The request provides:

- \$1.02 billion for ASPR's Biomedical Advanced Research and Development Authority (BARDA), including almost \$512 million for Advanced Research and Development (ARD) to support development of medical countermeasures (MCM) that address chemical, biological, radiological, and nuclear (CBRN) threats, \$192 million of which supports the combating antimicrobial resistant bacteria (CARB) initiative, and \$510 million for Project BioShield (PBS) to support late-stage development and procurements of MCMs;
- \$202 million for activities by ASPR to develop new diagnostics tools, vaccines, immunotherapeutics, and international preparedness for pandemic influenza (PI) and emerging infectious diseases;
- \$227 million for the Hospital Preparedness Program (HPP) to support cooperative agreements with state, local, and territorial health departments in order to improve surge capacity and enhance community health care coalitions;
- \$80 million for federal public health emergency management, the National Disaster Medical System (NDMS), and the Civilian Volunteer Medical Reserve Corps (MRC); and,
- \$46 million for ASPR's policy and planning, acquisitions, grants, and financial management, administrative operations, and leadership.

Developing Medical Countermeasures Against Threats to Americans' Health: \$511.7 Million: The budget request for ARD is \$511.7 million, which is level to FY 2017. Since its inception in late 2006, BARDA has supported advanced research and development of more than 190 CBRN and PI MCM product candidates. As of 2016, BARDA has supported 21 products under PBS; 14 have already been delivered to the Strategic National Stockpile

(SNS) with the remaining candidates to be delivered in the near future. Six of the candidates have already achieved licensure/ approval by the Food and Drug Administration. Candidates are supported under ARD or PBS to address the 13 threats identified by the Department of Homeland Security and prioritized in the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan (2016). BARDA continues to fund broad spectrum antimicrobials, antiviral drugs, and vaccine candidates against the Ebola and Marburg viruses. BARDA also funds platform biodiagnostics devices designed to confirm infection with biological agents and candidate products including thermal burns products, novel antibacterial drugs, diagnostics, and vaccines for injury or illness from radiological or nuclear incidents.

Spotlight: ASPR Impacts Thermal Burns: Each year, burn injuries lead to over 500,000 emergency department visits and about 50,000 hospital admissions. These burn-related injuries result in approximately 4,000 deaths annually. ASPR leads on-going and planned activities related to treatment and systems capability associated with thermal burns. Projects funded by BARDA that address thermal burns have progressed significantly, with four candidates transitioning to late-stage development and acquisition under Project BioShield in FY 2015. The burn products supported under PBS are maturing and entering/ have entered Phase III clinical trials. The products are also being used in Europe and the U.S. to address burn injuries resulting from fires or explosions. BARDA's goal is to develop candidate products that can be incorporated into the routine care for burn patients, thus improving patient outcomes and making the products commercially available if they are needed during a response to a terrorist incident. ASPR is developing an inventory of the emergency care capabilities of the health care system. This work includes the development of a network platform for reporting immediate and surge burn bed availability to match patient acuity or critical providers in the network. This is important because any large burn event, such as a large structure fire, chemical accident, or nuclear detonation, may result in hundreds or thousands of burn patients. During such events, the delivery of optimal burn care requires specialized equipment and experienced personnel. Within an hour, a quarter of Americans have access to burn centers by ground ambulance, and 54 percent have access by air ambulance. Within two hours, these figures rise to 46.3 percent and 79 percent by ground or air ambulance, respectively. ASPR, through the Technical Resources, Assistance Center, and Information Exchange (TRACIE), partnered with the American Burn Association to conduct national drills focused on assessing hospital burn bed capacity.



The FY 2018 budget request includes \$192 million, which is level with FY 2017 funding, for the CARB initiative. During FY 2018, ASPR's BARDA will continue utilizing innovative public-private partnering mechanisms to form relationships with pharmaceutical and biotech companies that are developing antibacterial therapies. ASPR is using these innovative partnerships with small and large pharmaceutical and biotechnology companies to develop promising, cutting-edge antibacterial therapies that will improve patient care and preparedness across the United States. ASPR is supporting the development of the first new classes of antibiotics to treat multidrug-resistant pathogens that are sometimes called superbugs. ASPR also anticipates supporting nontraditional antibacterial therapy(s) (e.g., monoclonal antibody, microbiome modulation), in alignment with the CARB National Strategy.

Spotlight: CARB-X: In July of 2016, BARDA and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, established the Combatting Antibiotic Resistant Bacteria Accelerator (CARB-X), a novel public private partnership aimed at promoting pre-clinical innovation in antibacterial drug, vaccine, devices, and diagnostic development to enhance national security. CARB-X is a collaboration among Boston University, BARDA, NIAID, and the Wellcome Trust. CARB-X brings together three life science accelerators with the aim to identify, build, and manage a portfolio of innovative antibacterial MCMs. In March 2017, CARB-X held the *Powered by CARB-X* Launch Event to announce the first set of companies to receive CARB-X support. The announcement included the Wellcome Trust contributing \$155 million from its own charitable organization over five years. This contribution is in addition to BARDA support of up to \$250 million over five years. The initial CARB-X portfolio includes 11 new products, three of which are entirely new classes of antibiotics. Four companies are pursuing alternatives—non-antibiotic based technologies designed to treat drug resistant bacterial infections. In 2017-2018, CARB-X will add candidates to the portfolio. In FY 2016, BARDA and NIAID collaborated to establish the Antimicrobial Resistance Diagnostic Challenge, a federal prize competition that will award up to a total of \$20 million in prizes for innovative rapid, point-of-need diagnostic tests to combat the emergence and spread of drug resistant bacteria. In March 2017, 10 semifinalists were selected

amongst 74 submissions for their concepts for a diagnostic based on a technical and programmatic evaluation and will each receive \$50,000 to develop their concepts into prototypes.

Project BioShield \$510 Million: The budget request for Project BioShield of \$510 million is level to FY 2017 funding. Through Project BioShield, BARDA will make five procurements: new antimicrobial drugs to address biothreat pathogens, a new acute radiation syndrome MCM, new biodiagnostic for anthrax, a new high-throughput biodosimetry diagnostic device, and additional Ebola therapeutic and vaccine candidates.

In FYs 2014-2016, BARDA replenished expiring stockpiles of existing anthrax antitoxins for inhalational anthrax and smallpox MVA vaccine. These vaccines are designed for people with weakened immune systems, such as those with HIV or atopic dermatitis. In FY 2017, BARDA is replenishing stockpiles of the licensed anthrax vaccine to ensure the U.S. maintains the appropriate preparedness posture against anthrax until the next generation anthrax vaccine is ready for inclusion into the SNS formulary.

Pandemic Influenza \$202.862 Million: The FY 2018 budget requests \$202.862 million, which is a \$135 million increase above FY 2017 funding. The request includes \$3 million in annual funding for international policy and diplomacy programs and \$199.86 million for BARDA Pandemic Influenza MCM programs. The FY 2018 funds will advance critical MCMs using Other Transaction Authority agreements in both therapeutic drugs and universal influenza vaccine development with the focus on platform technologies.

To improve preparedness, protect health, and save lives during a pandemic, BARDA continues to support the advanced development of antiviral drugs for those who are severely ill, a critical unmet medical need. As established in the National Strategy for Pandemic Influenza, BARDA maintains a preparedness posture of domestic egg-recombinant and cell-based vaccines capability and capacity. BARDA has made substantial investments in developing this capacity toward the goal of 600 million vaccine doses available six months from the declaration of a pandemic. BARDA accomplished the previously set goal of 500 million doses in FY 2016 and will accomplish the goal of 575 million vaccine doses during FY 2017. In FY 2018, BARDA will pursue platform-based vaccine technologies for rapid response to pandemic threats and ongoing developments of universal influenza vaccine. Over the past decade, efforts to identify and resolve barriers that meet the need for the MCMs used for pandemic influenza expanded the capacity to develop MCMs for other emerging infectious diseases, such as Ebola and Zika.

BARDA has advanced detection and diagnostic capability in both specific and rapid detection devices. These devices are currently being used in near-patient and point-of-care settings, such as physician's offices and hospitals. The ultimate goal for BARDA is to empower patients by moving toward a fast, real-time, intelligent network-based diagnostic device in-home for influenza detection.

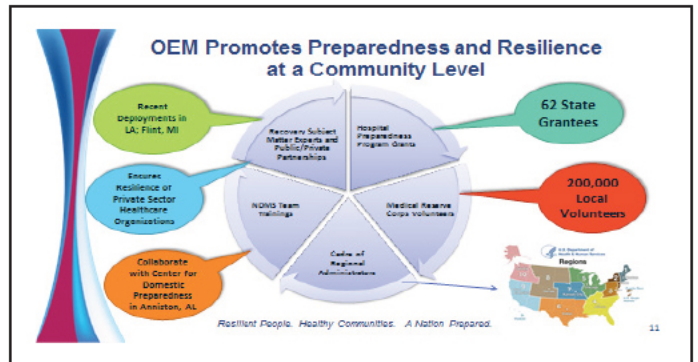
Spotlight on H7N9: During the winter of 2016-2017, China experienced the largest epidemic of Avian Influenza (H7N9) since emerging in 2013. During the 2013 outbreak, BARDA led the development, manufacturing, and clinical testing of new vaccines as part of the HHS's pre-pandemic vaccine stockpiling program. In 2017, consistent with World Health Organization recommendations, BARDA began developing new vaccines to respond to the new variant of the H7N9 virus so that the United States would be ready in case the virus leads to a pandemic. The virus is of particular concern because it can cause death in infected poultry and humans and because the virus appears to be resistant to antiviral medications normally used to treat people hospitalized with influenza infections. To protect public health and save lives in the next pandemic, BARDA must maintain momentum in developing and stockpiling effective vaccines, therapeutics, and diagnostics. BARDA created a nimble and responsive National Pre-Pandemic Influenza Vaccine Stockpile and developed a robust testing program to monitor the potency, safety, and efficacy of the stockpiled products to improve the nation's preparedness for influenza viruses that have pandemic potential emerging and circulating anywhere in the world.

Regional, State and Local Preparedness \$307.6 Million: ASPR provides critical operational leadership and support through a comprehensive emergency management program while administering and executing the Department's responsibilities to respond and recover during all major public health and medical incidents on behalf of the federal government. ASPR is vital to fulfilling HHS responsibilities for public health emergencies.

HHS is the primary coordinating agency for Public Health and Medical Emergency Support Function-8 of the National Response Framework and the Health and Social Services Recovery Support Function of the National Disaster Recovery Framework. It can serve as the lead federal agency in coordinating the federal response to biological incidents. ASPR also holds the designation as the lead federal agency for these components in the Emergency Support Function Leadership Group as well as the Recovery Support Function Leadership Group.

Preparedness and Emergency Operations \$24.607 Million: The FY 2018 Budget includes \$24.607 million in budget authority for Preparedness and Emergency Operations activities. This request is a decrease of \$47,000 from the FY 2017 funding level. The request supports the Office of Emergency Management's (OEM) preparedness activities to be able to immediately respond to a public health emergency or medical incident. This funding supports critical incident management and operational coordination through the Secretary's Operation Center as well as development of operational plans and procedures that OEM undertakes with key stakeholders as part of ASPR's role as the lead for all public health and medical disaster response and recovery efforts from across the federal government. Included in the total is \$5 million to support National Special Security Events and other public health emergencies that may not have funds provided under a Stafford Act declaration. These include known events such as the State of the Union address and the Presidential Inauguration.

Figure 1. OEM promotes preparedness and resilience



National Disaster Medical System \$49.809 Million: The FY 2018 budget request is \$49.809 million in budget authority, a decrease of \$95,000 from the FY 2017 level. Funding supports NDMS operations and regional emergency coordination to prepare and respond to public health emergencies. Additionally, funding is used for resource management, mutual aid, and logistics, which includes NDMS teams, supplies, and equipment. Lastly, the request strengthens federal response capabilities by investing in annual team trainings and incorporating stakeholders into existing trainings. In FY 2017, NDMS deployed to provide support for Hurricane Matthew, the Louisiana flood, the 45th Presidential Inauguration, and ongoing operations in Puerto Rico for the federal Zika response.

Hospital Preparedness Program (HPP) \$227.201 Million: The FY 2018 budget requests \$227.201 million for HPP, which is a decrease of \$27.354 million below the FY 2017 level. Funding will support HPP cooperative agreements for states and high-risk political subdivisions. Funding also supports administration, performance evaluation and oversight of the cooperative agreements, as well as other programs at ASPR that directly support the mission of HPP. These programs include TRACIE; the Emergency Care Coordination Center; Critical Infrastructure Protection, and the Division of Recovery.

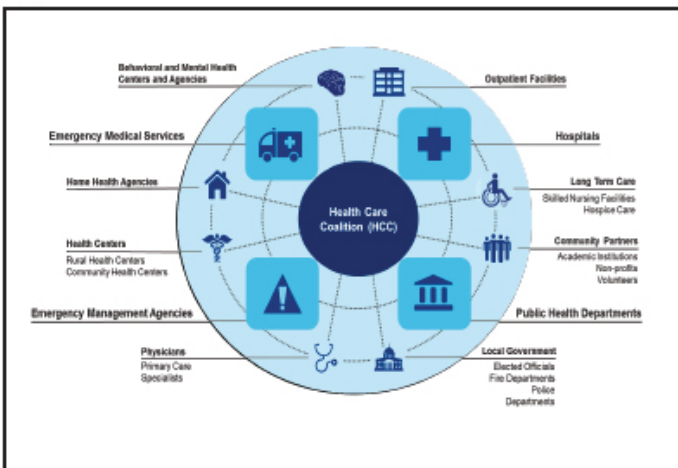
In FY 2018, a new funding formula will be used to determine HPP awards based on population and risk to drive strategic advancements in health care delivery system readiness and leverage private sector ideas and best practices in ways that enhance government efficiency and accountability. HPP will continue to encourage its awardees to form and develop health care coalitions (HCCs) to further the vision of collaborative and coordinated regional health care delivery system preparedness and response. The innovations and improvements are as follows:

- **Define the target market:** By continuing to incorporate FEMA's State Homeland Security Program risk score, as well as improving HPP's natural disaster risk score calculation in its funding distribution formula, ASPR will be targeting federal funding to those states and jurisdictions at greatest risk, creating a leaner, more effective HPP.

- **Innovate through competition:** ASPR proposes state and jurisdiction-level competition for HPP funds by allowing state and directly funded city government public health departments, academic medical centers, and state and local hospital associations to apply and compete to serve as the awardee for their jurisdiction.
- **Accelerate results through accountability:** Excellent performance should be rewarded and poor performance corrected. By instituting updated performance measures, HPP will be able to better evaluate and analyze funding impact. This change allows the program to objectively track trends in health care delivery system preparedness and response coordination, communication, patient care, and continuous learning and improvement.

Spotlight on Health Care Coalition Coordination: As Hurricane Matthew barreled toward Georgia, local HCC members turned to their strong coastal evacuation plan. The plan was developed based on lessons learned through years of HPP-funded exercises and incorporated numerous agreements with health care and other partners essential for moving patients across Georgia. Five days before hurricane landfall, the HCC began coordinating situational awareness among members and partners, allowing ample time for collaborative, informed decision-making. In the critical 24 hours before landfall, the HCC evacuated over 1,200 patients – some just out of surgery – without any loss of life. One HCC member shared that, “HPP enables critical partnerships to be formed and tested before a disaster. We would not have successfully evacuated over a thousand patients – some in extremely vulnerable condition – in 24 hours without our HCC and HPP.”

Figure 2. Health Care Coalition Network



Medical Reserve Corps \$5.989 Million: The FY 2018 Budget for the civilian volunteer MRC is \$5.989 million, which is a decrease of \$11,000 from the FY 2017 level. Funding will support regional coordination and technical assistance to MRC unit leaders to guide the development of the units. Funding also will be used to identify the key missions and/or functional areas most often supported by MRC units (including shelter support, mass vaccination, medical countermeasure dispensing) and to develop a system to track, monitor and assess units’ ability to support the mission and the extent to which they can assist. In addition, funding will be used to identify a standardized set of “Mission Ready Packages” that could be used by local and state officials to characterize and type the MRC resources available. Recently, MRC units have deployed to Zika prevalence areas such as Puerto Rico, Florida, and Texas. Additionally, they have deployed to assist in recovery efforts related to flooding in Louisiana.

ASPR Operations \$30.879 Million: The FY 2018 Budget for ASPR’s Operations is \$30.879 million, which is a decrease of \$59,000 from the FY 2017 level. Operations supports the stewardship of public resources, the development of a world class workforce, risk management and mitigation, communications, legislation, and provides decisive leadership to ensure the nation’s health security.

Office of Policy and Planning (OPP) \$14.849 Million: The FY 2018 funding request for ASPR’s OPP is \$14.849 million, which is a decrease of \$28,000 from the FY 2017 funding level. OPP leads disaster policy development and coordination across ASPR and the Department. OPP leads policy coordination for preparedness and response across federal, state, and local governments, the private sector, academia, and international partners. OPP also leads a public-private transparency initiative to provide a portal for scientists, laboratory staff, policy makers, and the public to locate federal and non-federal resources on biorisk management. During FY 2016-2017, OPP trained scientists and biosafety officers about biosafety and biosecurity practices.

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